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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/663,623 | 09/16/2003 | John Vanden Hock | 11998.55US01 | 1901 |
| 25764 | 7590 | 05/03/2006 | EXAMINER | |
| FAEGRE & BENSON LLP PATENT DOCKETING 2200 WELLS FARGO CENTER MINNEAPOLIS, MN 55402 | | | | KRAMER, NICOLE R |
| ART UNIT | | PAPER NUMBER | | |
| | | 3762 | | |

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/663,623 | HOEK ET AL. | |
| | Examiner | Art Unit | |
| | Nicole R. Kramer | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 March 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
 - 4a) Of the above claim(s) 19-24 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-8 is/are rejected.
- 7) Claim(s) 9-18 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/8/2004; 2/13/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Claims 19-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 3/21/2006.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S Patent No. 5,702,343 ("Alferness").

Alferness discloses a method for applying a cardiac support device to a heart of a mammal (Alferness is directed to a cardiac reinforcement device or CRD), the method comprising: (a) surgically accessing a heart (the CRD can be applied to the epicardium of a heart through a thoracotomy or through a minimally invasive procedure through a thorascopic incision; see col. 5, lines 54-59); (b) providing a cardiac support device including a jacket (CRD may be jacket 15; see Fig. 3 and associated text); and (c) positioning the jacket around at least a portion of the heart by applying a pulling force to the jacket (the size of jacket 15 is adjusted by moving opposing edges of slot 19 closer

together via fasteners 22 and 23; see col. 4, lines 52-65 and col. 6, lines 29-39. In order to move the opposing edge of the slot closer together, a pulling force is necessarily applied to fasteners 22 and 23).

With respect to claim 3, as described above, Alferness discloses that the size of jacket 15 is adjusted by moving opposing edges of slot 19 closer together via fasteners 22 and 23; see col. 4, lines 52-65 and col. 6, lines 29-39. In order to move the opposing edges of the slot closer together, a first pulling force is necessarily applied to fasteners 23 in a direction towards opposing lateral edge 21 and a second pulling force is necessarily applied to fasteners 22 in a direction towards opposing lateral edge 20 to adjust the jacket around the heart.

4. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S Patent No. 6,193,648 ("Krueger").

Krueger discloses a method for applying a cardiac support device to a heart of a mammal, the method comprising: (a) surgically accessing a heart (see col. 6, lines 41-45); (b) providing a cardiac support device including a jacket (jacket 10 is applied over the apex of the heart; see col. 6, lines 41-45); and (c) positioning the jacket around at least a portion of the heart by applying a pulling force to the jacket (the size of jacket 10 is adjusted by selectively pulling on free ends 35 of drawstrings 32; see col. 8, lines 64-66).

With respect to claim 3, Krueger discloses that the surgeon can pull on free ends 35 to tension the jacket 10, and can release or reduce the degree of tensioning by

bending or stretching the associated springs 30 (see col. 9, lines 12-30). Examiner considers "pulling in a first direction a first portion of the jacket" to encompass pulling on free ends 35 to tension the jacket 10, and "pulling in a second direction a second portion of the jacket" to encompass bending or stretching the springs 30 to reduce the amount of tensioning.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No. 5,702,343 ("Alfernness").

As described above, Alfernness discloses that the size of jacket 15 is adjusted by moving opposing edges of slot 19 closer together via fasteners 22 and 23; see col. 4, lines 52-65 and col. 6, lines 29-39. In describing how the CRD is applied to the epicardium of a heart, Alfernness discloses that a placement tool can be used to apply the CRD over the heart through a minimally invasive thorascopic incision (see col. 5, line 54 - col. 6, line 10; see also Fig. 7 and associated text at col. 7, lines 25-33 for a description of a placement tool 60 for placing the CRD jacket around the epicardium of the heart). After the CRD is in position over the epicardial surface, a second incision is made to provide access for suitable surgical instruments to secure or adjust the size of

the CRD (see col. 6, lines 8-10). Alfernness fails to specifically disclose that the second incision is made from a position superior to the heart and/or delivery device. Since the size of jacket 15 is adjusted by moving opposing edges of slot 19 closer together via fasteners 22 and 23, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention for the second incision for providing access for suitable surgical instruments to secure or adjust the CRD to be from a position superior to the heart and/or delivery device, because the pulling forces to secure and/or adjust the cone-shaped CRD are necessarily upwards (in order to secure the broader base of the jacket around the base portion of the heart, and secure the apex of the jacket around the apex of the heart as described at col. 4, line 11-22) and towards the opposing side of the slot (in order to selectively adjust the size of the jacket as previously described) in order to securely fit the CRD jacket over the surface of the heart and thus may be most effectively performed from an incision location superior to the heart and delivery device incision.

With respect to claims 6 and 8, as described above, in order to move the opposing edges of the slot closer together, a first pulling force is necessarily applied to fasteners 23 in a direction towards opposing lateral edge 21 and a second pulling force is necessarily applied to fasteners 22 in a direction towards opposing lateral edge 20 to adjust the jacket around the heart. Further, Alfernness discloses suitable surgical instruments are utilized to secure or adjust the size of the CRD (see col. 6, lines 8-10). In order to utilize a surgical instrument to manipulate fasteners 22 and 23, the surgical instrument must grasp the fasteners, which are strands secured to the jacket.

With respect to claim 7, Alfernness fails to disclose removing the tool from the thorax and surgically inserting the tool into another location in the thorax in a position superior to the delivery device in order to use the tool to pull in a second direction. As previously noted, in order to move the opposing edges of the slot closer together, a first pulling force is necessarily applied to fasteners 23 in a direction towards opposing lateral edge 21 and a second pulling force is necessarily applied to fasteners 22 in a direction towards opposing lateral edge 20 to adjust the jacket around the heart. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to make another incision for applying the second pulling force because the second pulling force is necessarily in the opposite direction as the first pulling force (that is, towards the opposite lateral edge of the slot) and thus may be more effectively performed from a different incision location.

Allowable Subject Matter

7. Claims 9 (and 10-18 depending therefrom) are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
8. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest a cardiac jacket comprising (A) a first anterior strand secured to the base edge adjacent to first lateral edge; (B) a second anterior strand secured to the base edge adjacent to the second lateral edge; (C) a first posterior strand secured to the base edge and positioned closer to the first

anterior strand than to the second anterior strand; and (D) a second posterior strand secured to the base edge and positioned closer to the second anterior strand than to the first anterior strand, wherein the step of positioning the jacket around at least a portion of the heart includes pulling each of the first anterior, second anterior, first posterior, and second posterior strands to pull the jacket around the heart.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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4/26/06

G. M.
George Manuel
Primary Examiner